Fingertip Pulse Oximeter
Geratherm® oxy control GT-300C203

Geratherm Medical AG
Germany

Instruction manual

Read carefully before using.

General Description

Haemoglobin saturation is the percentage of oxygen-bearing haemoglobin (HbO2) molecules in proportion to the amount of oxygen that the haemoglobin (Hb) is capable of carrying in the blood. It expresses the concentration of oxyhaemoglobin in the blood and is a very important parameter of the respiratory and circulation system. Many respiratory diseases can result in a decline in haemoglobin saturation levels. In clinical medicine it is very important to determine a patient's haemoglobin saturation level in good time so as to detect problems sufficiently early.

Pulsoximetry is a non-invasive monitoring procedure for the determination of oxygen saturation in arterial (oxygenated) blood by means of a photosensor.

To obtain a diagnosis, it is only necessary for the patient to insert a finger into a fingertip photoelectric sensor, whereupon a display screen directly shows the measured value of haemoglobin saturation. Clinical experiments have demonstrated the high degree of precision and repeatability of this procedure.

Precautions for Use

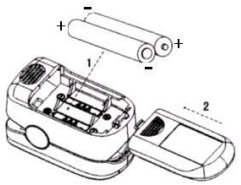
1 Do not use the pulse oximeter in an MRI or CT environment.
2 Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
3 The pulse oximeter is intended only as an ancillary procedure in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
4 Prolonged use or the patient's condition may require that the sensor site be changed periodically. Change the sensor site and check the patient's skin integrity, circulatory status, and correct alignment at least every 4 hours.
5 Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid, which will result in inaccurate readings.
6 Preserve the pulse oximeter in a dry environment.
7 The following factors may impair the SpO_2 measurements and/or lead to inaccurate readings:
- Significant levels of dysfunctional haemoglobins (such as carboxy-haemoglobin or methaemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- High levels of ambient light (shield the sensor area if necessary)
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- The patient has hypotension, severe vasoconstriction, severe anaemia, or hypothermia
- The patient is in cardiac arrest or is in shock
- Fingernail polish or artificial fingernails
- Cold or dirty fingernails

Scope of Product Operation

The Geratherm® oxy control can be used to measure human haemoglobin saturation levels and the heart rate via a finger. The product is suitable for use at home, in hospital (including clinical use in internal medicine/surgical wards, in anaesthesia, paediatrics, intensive care etc.), in social medical institutions or for physical care in sports (it can be used before or after sporting activity - use during sporting activities is not recommended).

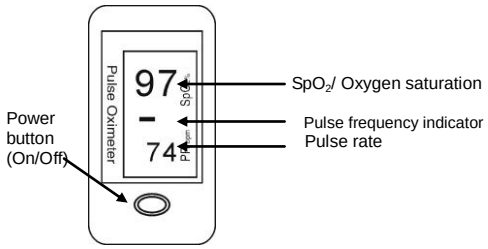
Battery Installation

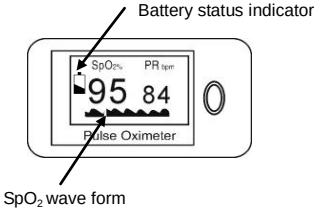
1. Place the two AAA batteries inside the battery compartment ensuring correct polarity.
2. Push the battery cover horizontally along the arrow as shown.



Notes: Batteries must be inserted with the correct polarities. Otherwise, damage might be caused to the device.
Please put or remove batteries in the correct order, or the device bracket may be damaged.
Please remove the battery if the oximeter will not be used for a long period.
When the battery status indicator appears, replace the batteries in good time.

Description of Front Panel

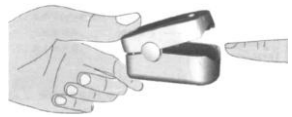




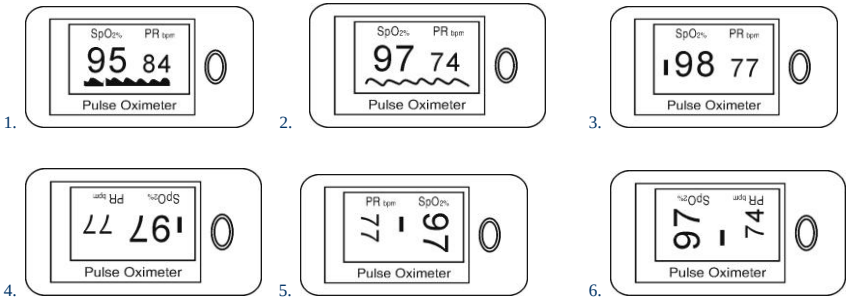
The pulse frequency indicator flashes on and off in accordance with the pulse rate displayed.

How to Use

1 Insert two AAA batteries into the battery compartment before replacing the cover.
2 Press the device at the rear end so as to open the front section for the insertion of a finger.
3 When your finger is in the oximeter, the nail surface must face upwards.
4 After inserting the finger let go of the rear end.
5 Press the power button on the front panel once.
6 While the oximeter is working, you should not move your finger and you should behave in a calm manner.
7 Read the values shown on the display screen.



After turning on the oximeter, each time you press the power button the oximeter will switch to another display mode. There are 6 display modes shown as follows:



If you press the power button for a long time (longer than 1 second), the brightness level of the oximeter will gradually change. There are 10 brightness levels. The default level is level four.

The PulseOximeter is supplied with a protective case to shield it from dirt and impacts.

Evaluation of pulse oximetry

In healthy patients, oxygen saturation levels lie between 96 and 98 %. Values below 95 % can indicate a health disorder and make it necessary to supply the patient with additional oxygen.
If your oxygen saturation value is below 95 %, please consult your physician.
Normal pulse values depend on the age and fitness level of the individual.
Here are a few reference values indicating normal pulse rates:

- Infants under 1 year: 100 - 160 bpm
- Children between 1 and 10 years: 70 - 120 bpm
- People over 10 years: 60 - 100 bpm
- Highly trained individuals/athletes: 40 - 60 bpm

Specification

1. **Display Type:** 1-colour OLED display
2. **SpO_2:**
   Measurement range: 70-99%
   Accuracy：±2% between 80% and 99%; ±3% between 70% and 80%
3. **Pulse Rate:**
   Measurement range：30-235 bpm
   Accuracy：±2 bpm or ±2%（larger）
   Pulse intensity: Pulse frequency indicator
4. **Power Requirements:**
   Two AAA alkaline batteries, type AAA 1.5 V, 600mAh
   Power consumption: Less than 40mA
   Low power indication:
   Battery life: up to 30 hours in continual use
5. **Dimensions:**
   Length: 58mm; Width: 32mm; Height: 34mm
   Weight: 50g (including two AAA batteries)
6. **Environmental Requirements:**
   Operating temperature: 5-40℃; Storage temperature: -10 – +40℃
   Humidity: 15%-80% in operation; 10%-80% in storage
7. **Quality Standards:**
   Certification according EN ISO 13485, Conformity according EN ISO 9919:2005 Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use, EN60601-1, EN60601-1-2, standard Council Directives 93/42/ EEC

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO2 or PR cannot be shown normally.	1. Finger is not inserted correctly. 2. Patient's oxyhaemoglobin level is too low to be measured.	1. Try inserting the finger again. 2. Try several more times if you are sure that there is no problem with the device. Please go to a hospital in good time to obtain a precise diagnosis.
SpO2 or PR is shown unstably	1. Finger might not be inserted far enough. 2. Finger is trembling or the patient's body is moving.	1. Try inserting the finger again. 2. Try not to move.
The oximeter cannot be switched on	1. Battery power may be inadequate or not be there at all. 2. Batteries may have been inserted incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries. 2. Please reinsert the batteries. 3. Have the device tested by the manufacturer
Indication lamps suddenly go off	1. The product is automatically switched off if no signal is detected for longer than 8 seconds. 2. Low power/ Batteries empty	1. Normal 2. Replace the batteries.
"Error3" or "Error4" displayed on screen	1. Low power/ Batteries empty 2. Receiving sensor shielded or sensor damaged.	1. Insert new batteries. 2. Have the device tested by the manufacturer.
"Error7" displayed on screen	1. Low power/ Batteries empty 2. Infrared sensor damaged.	1 Change the batteries. 2 Have the device tested by the manufacturer.

Cleaning Instructions

Please use medical alcohol to clean the synthetic material touching the finger inside the oximeter, and clean the test finger before and after using.
Please clean the surface of pulse oximeter for every use.

Limited Warranty

This pulse oximeter is guaranteed for 2 years from the date of purchase against manufacturer's defect under conditions of normal use.
Following the instructions precisely will ensure that the device functions reliably for many years.
If your pulse oximeter does not function properly due to defective parts or assembly we will repair it free of charge. All parts are covered by this warranty. The warranty does not cover damage to your unit due to improper handling.
The manufacturer recommends that the accuracy of the device be checked by an authorized laboratory every 2 years.

Adhere to the applicable regulations when disposing of the device.

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